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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,559	11/19/2003	Chon-Ho Yen	YENC3003/EM	5053
23364	7590	07/10/2006	EXAMINER	
BACON & THOMAS, PLLC 625 SLATERS LANE FOURTH FLOOR ALEXANDRIA, VA 22314			MENON, KRISHNAN S	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



## DETAILED ACTION

Claims 1-6, 8-10, 13-23 and 25-32 are pending as amended 6/22/06

### *Claim Objections*

Claim 13 objected to because of the following informalities: indent © appears to be a typo for (c). Appropriate correction is required.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-5 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denman et al (US 5,756,687) in view of Dieu et al (US 4,897,277).

Denman teaches a method of filtering animal milk to separate casein by adjusting the pH to a value, like 5 (column 5 line 62 - 6 line 32), and using a filter of pore size 0.2-5  $\mu\text{m}$  (column 7 line 50-65). Centrifugal pre-treatment is taught in the examples. Animal is transgenic – column 4 lines 33-43. Denman differs from the claims in the recitation of the 10-20 psi pressure for filtration. However, it would be obvious to one of ordinary skill in the art at the time of invention to provide adequate operating pressure for the filtration process. A prima facie case under 35 U.S.C. 102 /103 could be made if a process step is inherent: *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433

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(CCPA 1977) (Applicant claimed a process for preparing a hydrolytically-stable zeolitic aluminosilicate which included a step of "cooling the steam zeolite ... at a rate sufficiently rapid that the cooled zeolite exhibits a X-ray diffraction pattern ...." All the process limitations were expressly disclosed by a U.S. patent to Hansford except the cooling step. The court stated that any sample of Hansford's zeolite would necessarily be cooled to facilitate subsequent handling.

The claims also differ from the teaching of Denman in the recitation of the non-electrical-charged filtering membrane for filtration. Denman is silent on the type of membrane to be used. Dieu teaches using a ceramic membrane for filtration of milk proteins, like what is used by the applicant – see abstract and column 1 lines 58-67 and column 2 lines 63-66. It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Dieu in the teaching of Denman because Dieu teaches the use of the ceramic membrane for the various advantages such as ease of sterilization, reduced clogging, ease of periodic unclogging, commercial availability, etc., - column 1 lines 35-57.

2. Claims 6, 13-19,22,23,25-28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denman et al (US 5,756,687) in view of Dieu as applied to claim 1 above and further in view of Mahmoud et al (US 6,051,268).

Denman in view of Dieu teaches a method of separating and purifying casein, proteins, peptides or human coagulation factor IX from animal milk (column 3 lines 29-62, column 4 lines 25-32, column 5 lines 15-20) comprising adjusting pH to 5 by a buffer

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(column 5 line 62 – column 6 line 32), plurality of techniques including filtration and chromatography (column 7 lines 6-40), (column 7 lines 42-65), with chromatographic method for further purifying the target substance (column 7 lines 6-40). Animals are transgenic (column 4 lines 33-43).

Claims differ from the teaching of the references in the recitation of diafiltration, two separate filtration steps, fat removal by centrifugation and the diafiltration mode. Even if Denman teaches plurality of techniques including filtration, it is not specific about having two separate filtration steps. Mahmoud teaches that diafiltration is conventional to use diafiltration method to remove salts and lactose from milk to concentrate proteins to high purity. Multiple filtration steps are taught by Mahmoud for fractionating and separating components of milk such as casein (column 5 lines 59-67), and proteins by molecular weight (column 7 lines 25-60). Mahmoud teaches Fat removal by centrifugation and Diafiltration mode is taught as conventional (see column 1 lines 38-45). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Mahmoud in the teaching of Denman in view of Dieu to fractionate the milk protein as desired by the various filtration steps as taught by Mahmoud.

With respect to the operating pressure of 10-20 psi, inherent process step – in re Best.

3. Claims 20-21 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denman et al (US 5,756,687) in view of Dieu and Mahmoud as applied to claim 13 above in paragraph 2 and Roesink et al (US 4,798,847).

Claims 20-21 and 30-32 differ from the material of the second membrane – polysulfone. However, Denman teaches that any material suitable for filtering milk could be used for the process. Roesink teaches polysulfone hydrophilic microfiltration and ultrafiltration membranes with varying and tailored pore sizes (column 1 lines 25-37 and column 2 lines 41-45; examples) specifically made for applications such as milk and dairy products, blood, etc (column 1 lines 47-51). One would use the teachings of Roesink in the teaching of Denman in view of Dieu and Mahmoud because Roesink membranes have high temperature stability, chemical resistance and mechanical strength, suitable for proper sterilization; because they can be made flat sheet, hollow fiber or tubular (see Roesink column 2 line 65 – column 3 line 9) and are specifically for milk and dairy industry applications, and also provides appropriate pore sizing. Molecular weight cut off can be optimized as taught by Mahmoud – see column 7 lines 26-60 of Mahmoud.

### ***Response to Arguments***

Applicant's arguments filed 6/22/06 have been fully considered but they are not persuasive.

With respect to the Dieu reference, the anticipation rejection is withdrawn, because the examiner recognizes that the pH in the Dieu reference at the ultrafiltration stage would be less than 4.6.

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Rest of applicant's arguments are on what the supporting references do not teach, which are not commensurate in scope with the claims and the rejection. They are also moot because of the new grounds for rejection.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

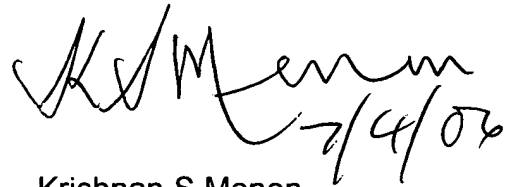
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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A handwritten signature in black ink, appearing to read 'K S Menon', followed by the date '7/4/06' written in a similar cursive style.

Krishnan S Menon  
Examiner  
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